Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Aug 2026

Phase III Trial Comparing Filgrastim (AryaTinaGene) to Neupogen (Amgen) in the Prevention of Neutropenic Complications in Breast Cancer Patients in Pange-Azar hospital of Gorgan

Protocol summary

Summary

This randomized, double-blind, phase III trial compared Tinagrast (AraTinaGene) and Neupogen (Inovator by Amgen) for the prevention of neutropenic complications in patients with breast cancer receiving chemotherapy. Patients with breast cancer are randomized into two parallel groups (n=50 per each groups) and receive 5 micrograms per kg body weight of either filgrastim-ATG or neupogen subcutaneously (s.c.) daily. Following administration of chemotherapic agents in day1 of 21-days cycles, patients receive filgrastim beginning on day 2 until day 7. Absolute neutrophil counts and other parameters are determined in both groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062613776N1**
Registration date: **2013-07-05, 1392/04/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-05, 1392/04/14

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

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hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arya Tina Gene Biopharm Co

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2013-11-01, 1392/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase III Trial Comparing Filgrastim (AryaTinaGene) to Neupogen (Amgen) in the Prevention of Neutropenic Complications in Breast Cancer Patients in Pange-Azar hospital of Gorgan

Public title

Clinical efficacy of Filgrastim-AryaTinaGene

Purpose

Other

Inclusion/Exclusion criteria

The study population consisted of women ≥ 18 years of age with metastatic or localized histopathologically proven breast cancer. Patients with localized cancer were required to have ≥ stage II disease with ≥ 1 positive regional node. Additional inclusion criteria included: Karnofsky performance status ≥ 70% for patients ≤ 70 years of age and ≥ 90% for patients > 70 years of age; adequate hematologic function (absolute neutrophil count [ANC] ≥3000 cells/µL, platelet count >100,000/µL, hemoglobin [Hb] ≥ 8 g/dL); adequate hepatic function (bilirubin ≤ 1.5 × upper limit of normal

[ULN], aspartate aminotransferase and alanine aminotransferase ≤ 2.5 × ULN, alkaline phosphatase ≤ 5 × ULN); creatinine ≤ 2.0 × ULN; and normal cardiac function as determined by MUGA (multiple-gated acquisition) scan or echocardiography. All hematologic, renal, and hepatic valueshad to be within institutional normal limits in patients > 70 years of age. All women who had received prior chemotherapy must have completed treatment at least 3 weeks prior to study drug administration, and women of child-bearing age had to agree to comply with effective contraception and have done so since their last menses. Patients who had received radiotherapy within 4 weeks of entry required special permission from the study sponsors to enroll. Patients were excluded if they had received a cumulative lifetime dose of doxorubicin > 240 mg/m2 or epirubicin > 432 mg/m2, prior treatment with mitomycin-C or busulfan, or > 2 prior regimens of chemotherapy (excluding hormonal treatment). Additional exclusion criteria included a history of significant cardiac disease, arrhythmias, uncontrolled hypertension, recent myocardial infarction, or ischemia. Patients with human immunodeficiency virus infection, active hepatitis, or a history of a serious comorbid condition, uncontrolled metabolic disease, or psychiatric condition that would impair tolerance or evaluation of the study drug were also excluded.

Age
From **18 years** old to **90 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Golestan University of Medical Sciences

Street address
Gorgan, Shast cola road, Falsafi Building

City
Gorgan

Postal code

Approval date
2013-06-25, 1392/04/04

Ethics committee reference number
77392032906

Health conditions studied

1

Description of health condition studied
Neutropenia

ICD-10 code
D70

ICD-10 code description

Primary outcomes

1

Description
Days of severe neuropenia (ANC>200 per ul)

Timepoint
Every chemotherapy cycle

Method of measurement
Absolute neutrophil count (per ul of blood)

2

Description
Days of minor neuropenia (ANC>500-1000 per ul)

Timepoint
Every chemotherapy cycle

Method of measurement
Absolute neutrophil count (per ul of blood)

3

Description
Days of moderate neuropenia (ANC>200-500 per ul)

Timepoint
Every chemotherapy cycle

Method of measurement
Absolute neutrophil count (per ul of blood)

Secondary outcomes

1

Description
Occurance of febrile neutropenia

Timepoint
every chemotherapy cycle

Method of measurement
Fever of 38.5 C for at least 1 h and neutropenia less than 500 per ul

2

Description

Occurance of sepsis related to filgrastim

Timepoint

every chemotherapy cycle

Method of measurement

Blood analysis

3

Description

Occurance of increased hepatic enzymes related to filgrastim

Timepoint

every chemotherapy cycle

Method of measurement

Blood analysis

4

Description

Occurance of musculoskeletal pain related to filgrastim

Timepoint

every chemotherapy cycle

Method of measurement

Patient questionery

Intervention groups

1

Description

Invention was granlocyte-colony stimulating factor as recombinant product made by AryaTinaGene Biopharm Co namely Filgrastim-ATG for group A and Neupogen (Amgen) for group B as standard treatment. Administration of filgrastim 1 day after chemotherapy at least for 5 days and maximum for 14 days at a dose of 5 ug/kg/day and comparison of clinical outcomes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pange-Azar hospital of Gorgan

Full name of responsible person

Dr. Seyyed Reza Khandoozi

Street address

Gorgan ValiAsr Sq. Chemotherapy Center

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryaTinaGene Biopharm Co.

Full name of responsible person

Dr. Majid Shahbazi

Street address

Gorgan, Aghghala Industrial Zone, Sazandegi2

City

Gorgan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

AryaTinaGene Biopharm Co.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical sciences

Full name of responsible person

Hossein Amini

Position

Assistant Prof of Pharmacology dept, Ph.D

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty